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AMGEN

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11 February, 2000

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061,
Rockville, MD 20852

Attn: Desk Officer for FDA

Ref. Docket No.99N-1852
Postmarketing Studies for Human Drugs and Licensed Biological Products; Status Reports, Federal Register Vol. 64, No. 230, Wednesday, December 1, 1999.

Dear Sir/Madam:

Amgen appreciates the opportunity to comment on the above referenced proposed regulation. We recognize and support FDA's efforts to implement the provisions specified within the Food and Drug Administration Modernization Act of 1997 (FDAMA) and understand that this proposed change to 21 CFR 314 and 601 is initiated to address specific requirements of FDAMA. With regard to the proposed regulations we have the following comments:

1) While this proposal addresses the requirements put forth in Section 130(a) of FDAMA, the proposed new section 314.81(b)(2)(viii) seems to go beyond the letter, spirit and intent of what was negotiated as law. Specifically, this section would require "A status report of **any** postmarketing study not included under paragraph (b)2)(vii)of this section that is being performed by, or on behalf of, the applicant."

Section 130(a) of FDAMA amended the Federal Food, Drug, and Cosmetic Act to add new provisions for reporting postmarketing studies (section 506B). FDAMA required that "a sponsor of a drug that has entered into an **agreement** with the Secretary to conduct a postmarketing study of a drug shall submit to the Secretary within 1 year after the approval of such drug and annually thereafter until the study is completed or terminated, a report of the progress of the study ...". Amgen believes the scope of this requirement includes only those postmarketing studies a firm has **committed** to the FDA to perform. Requiring reports for **any** postmarketing study goes beyond FDAMA, represents an additional regulatory burden, and serves no meaningful purpose.

Therefore, Amgen recommends that proposed regulation 314.81(b)(2)(viii) "Status of other postmarketing studies" be removed from the final rule.

2.) Proposed 314.81(b)(2)(vii) and 601.70 state that an applicant should submit the status reports described under 314.81(b)(2)(vii)(a) "until the Agency notifies the applicant, in

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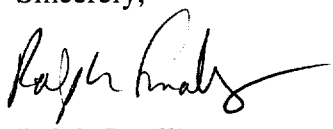
writing, that the study commitment has been fulfilled or acknowledges that the study is either no longer feasible or would no longer provide useful information". Amgen agrees with the Agency's proposal to document, in writing, its concurrence with an applicant's Dockets Management Branch conclusion that it has fulfilled its commitment, or that a commitment is either no longer feasible to fulfill, or would no longer provide useful information. Amgen believes that the Agency should establish a definitive timeframe for such documentation once an applicant has notified the Agency of the existence of one of these situations to eliminate any unnecessary reporting. A timeframe of 90 days is suggested.

3) Proposed 314.81(b)(2)(vii)(b) addresses public disclosure of information concerning a postmarketing study, stating that FDA may publicly disclose information needed to identify an applicant or establish the status of the study. The proposed rule further states "The information necessary to establish the status of a postmarketing study includes the study protocol, patient accrual rates, reports of unexpected suspected adverse drug reactions and study results". Amgen does not consider that: 1) the study protocol, 2) reports of unexpected suspected adverse drug reactions, or 3) results of a study are necessary to identify an applicant or establish the status of a postmarketing study. This information should not be publicly disclosed.

4) The term "post marketing studies" in Section 130(a) of FDAMA was meant to apply to Phase IV clinical studies which are negotiated as a condition of approval for an NDA or BLA drug product. This FDAMA requirement provides a mechanism for FDA to monitor these Phase IV clinical study commitments. We request that all reporting of non-clinical postmarketing studies (e.g., pre-clinical) be made optional for 21 CFR 601.70.

Again, thank you for the opportunity to provide comments on this Proposed Rule. If you have any questions regarding the above comments, please contact me at (805) 447-3058.

Sincerely,



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